DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

October 31, 2002

WARNING LETTER NYK 2003-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Nelson R. Irwin, President
CIDEC Corporation
1466 Clark St. Road
Auburn, New York 13021

Dear Mr. Irwin:

An inspection of your drug manufacturing facility located at 5776 Oakwood Road, Auburn, New York, conducted by Food and Drug Administration (FDA) investigators between September 3 and 12, 2002, found significant deviations from FDA's regulations establishing current good manufacturing practices (cGMPs) for finished pharmaceuticals (Title 21, Code of Federal Regulations [C.F.R.], Part 211). Such deviations cause the cow teat dips manufactured by your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 351(a)(2)(B).

Our investigators found the following deviations:

1) Your facility has no quality control unit, in violation of 21 C.F.R. § 211.22.

2) You have failed to test each lot of components for conformity with appropriate written specifications, as required by 21 C.F.R. § 211.84. The cGMP regulations allow you, as an alternative, to accept reports of analysis from the component supplier, but such reports were available for only one lot each of iodine concentrate and a buffer.

3) You have no written procedures that identify the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch, as required by 21 C.F.R. § 211.130. At least one finished product tote containing 220 gallons of CHX Plus Sanitizing Teat Dip lacked a lot number.

4) You have failed to conduct finished product testing on the CHX Plus Sanitizing Teat Dips, as required by 21 C.F.R. § 211.165(a).

5) You have failed to establish finished product test specifications for the CHX Plus Sanitizing Teat Dip and the Iodine Teat Dips, as required by 21 C.F.R. § 211.165(c).

6) You have failed to establish a written testing program designed to assess the stability characteristics of the teat dips, as required by 21 C.F.R. § 211.166(a).

7) You have failed to prepare batch production and control records, as required by 21 C.F.R. § 211.188. For example:

   a) There are no batch records for the CHX Plus Sanitizing Teat Dip, which your production sheets indicate was made on June 14, August 14, and August 30, 2002.

   b) You do not routinely record ingredient lot numbers.

8) You have failed to maintain complete laboratory records in compliance with 21 C.F.R. § 211.194(b). Specifically, there are no records documenting the reason for modifying the test for iodine and to verify that the results are as accurate and reliable as the previous method.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Please reply to this letter in writing within 15 working days of the steps you are taking to correct the violations. Correspondence concerning this matter should be directed to the Food and Drug Administration, 300 Hamilton Ave., White Plains, New York 10601, Attention: Richard T. Trainor, Compliance Officer.

Failure to correct these violations promptly may result in regulatory action, such as seizure and/or injunction, without further informal notice. In addition, FDA advises other federal agencies of the issuance of all Warning Letters about drugs and medical devices so that they may take this information into account when considering the award of contracts.

This letter is not intended to list all violations at your facility. As a manufacturer of finished pharmaceuticals, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

Sincerely yours,

for Jerome G. Woyshner
District Director

cc: Mr. Chris Cherry, Vice-President (Co-owner)
CIDEC Corporation
1466 Clark St. Road
Auburn, New York 13021